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| 09/939,406 | 08/24/2001 | Ben-Zion Dolitzky | 1662/49603 | 5473 |

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EXAMINER

BERNHARDT, EMILY B

| ART UNIT | PAPER NUMBER |
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1624

DATE MAILED: 12/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/939,406

Applicant(s)
DOLITZKY et al.

Examiner
Emily Bernhardt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/17/02.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36, 49, 51-63, and 65 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36, 49, 51-63, and 65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 6) ☐ Other:

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In view of applicant's response filed 10/17/02 the following applies.

Claims 1-36,49,51,52,55-57,59-61 and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

012 1. "Aryl" which remains in main claim 49 as well as many dependent claims of 49 as well as claim 1 is still unclear as to scope intended other than phenyl only described, exemplified in the instant specification. It is not agreed that such a term has a precise meaning. Note In re Sus 134 USPQ 301 regarding various meanings ascribed to the moiety. See footnote on the bottom of p.304. Thus in the absence of any definition in the instant specification, there remains an uncertainty as to intended scope.

012 2. While "aryl" has been removed in the R groups of main claim 1 it appears in many of the dependent claims. See 2,20-36,52,55 and 57.

012 3. It is not seen how claim 19 further limits the scope of claim 1. Note that claim 1 also now contains R3 at a fixed position. Thus claims dependent from these respective claims appear to be substantial duplicates as well. See 2-18 vs 20-36 and 51-52 vs 56-57.

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Claims 1-36,49,51-62 and 65 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection of the previous action is repeated notwithstanding applicant's remarks. ^① The specification solely relies on the disclosure of the US'848 patent for other examples of useful products obtained by the instant process employing instant piperazine precursors. The examiner has raised several points in the previous action regarding the scope of R variables still claimed and how they all can possibly be used to make mirtazapine and other piperazinoazepines none of which have been addressed except that the process claims do now require that R3 be adjacent to N-R1 site. Where is the "ample guidance" in the specification which applicant urges is present to make other useful piperazinoazepines? Specification **must** teach "how to use" not "find out how to use" as emphasized in In re Kirk 153 USPQ 48 . Also note Brenner v. Manson 148 USPQ 689; In re Diedrich 138 USPQ 128; In re Lorenz 134 USPQ 312 . All of these dealt with a failure of teaching how to use. Note Olivie and Nicholson do not reflect such a scope still claimed.

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

mm Claims 49, 58-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafon. While the examples in Lafon do not anticipate amended claims they are obvious variants since compounds in Lafon such as example 5 only differ in having a Me group in place of H on piperazino carbon. Note however that Lafon teaches both H and C1-2 alkyl as choices at this position. See definition of R2 in Lafon. Thus it would have been obvious to one skilled in the art at the time the invention was made to replace Me with H and in so doing obtain an instant compound for uses taught by Lafon.

Claims 2,4-10,20,22-28 remain rejected under 35 U.S.C. 102(b) as being anticipated by Olivie (US'452). While main claim has been amended to exclude "aryl" as a choice for R1 the dependent claims rejected herein still embrace this group.

Claims 49,58-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Toda (US'190) .Toda (cited and applied in parent) also anticipates some of the

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claims since R3 has been expanded to include alkyl as a choice which was originally claimed. See col.3, lines 14-15.

As R1=H is no longer claimed the rejection over Olivie and van der Burg is no longer applied. However, Nitta, newly cited in an IDS statement filed 8/13/02 for which a fee has been authorized under 37 CFR 1.17(p) is quite pertinent and thus applied below.

Claims 1,2,4-7,10,19,20,22-25,28,49,51,52,54,56-57,58-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Nitta (US'548). Nitta describes compounds within the instant scope and prepares such employing instant reactants in the presence of base (i.e. carbonate). See examples such as 1 and 3. Other piperazines prepared by alternate routes also read on compound claims. See example 2.

Claims 8,9,11-13,26,27,29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nitta in view of Olivie (US'452) and Winkley. The claims rejected herein require certain base and solvents to be used. Note that Nitta teaches a variety of solvents including some of those recited in claim 8 as can be seen from col.4 top paragraph, right column. Also bases other than carbonate used in the

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working examples pointed out in the above 102 rejection, are taught such as sodium amide as can be seen in col.4 as well. Additionally, the secondary references, Olive and Winkley, also teach for the same type of reaction, solvents such as DMF particularly claimed in claim 9. See example 1 in Olive and cols.6-7 of Winkley which discusses reaction parameters for step A process and teaches DMF in particular. Also the same bases as claimed herein are taught including NaH claimed in claim 13. Thus use of solvents and bases particularly claimed herein would be no more than an obvious expedient to one skilled in the art in view of their art-recognized equivalency in similar transformations as evidenced by the secondary references applied.

Claims 49,58-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Nishimura (abstract provided by applicants). The abstract discloses a compound within the instant scope. See compound printout on abstract page. A full copy of the article is being provided to show that instant process is not employed therein to make said compound.

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Claims 1-36,49,51-63, and65 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,339,156. Note that claim 54 is now also included since R1 has been amended to include tosyl among other choices. Applicants do not traverse this rejection but intend to file a terminal disclaimer if other matters have been resolved.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). Finality would also be deemed proper notwithstanding the new grounds of rejection applied above on claims not amended consistent with procedure set forth in MPEP 609 B(2) where IDS is provided after a first office action accompanied by a fee.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory

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action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.



EMILY BERNHARDT

PRIMARY EXAMINER

GROUP 1600